DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 3 0 2004

Partners in Biomaterials, Inc.
c/o Mr. James Christensen
466 W. Arrow Highway, Unit H
San Dimas, California 91773

Re: K040912
Trade/Device Name: Form Fit™ Hydrogel Canalicular Plug
Regulatory Class: Unclassified
Product Code: LZU
Dated: November 29, 2004
Received: October 28, 2004

Dear Mr. Christensen:

This letter corrects our substantially equivalent letter of November 16, 2004 regarding the regulation number and name. Our letter should have not reflected a regulation number and name as your device is currently unclassified.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21

CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K040912

Device Name: Form Fit Hydrogel Canalicular Plug

Indications For Use:

The Hydrogel Canalicular Plug is intended for use in patients experiencing dry eye symptoms such as redness, burning, reflex tearing, itching, or foreign body sensations, which can be relieved by blocking of the punctum.

The Hydrogel Canalicular Plug may be used in the treatment of dry eye syndrome and the dry eye component of various ocular surface diseases.

When indicated, the Hydrogel Canalicular Plug may be used after surgery of the eye to prevent complications due to dry eye and to enhance the retention of ocular medications on the eye. Patients experiencing dry eye related contact lens problems may also be aided by the Hydrogel Canalicular Plug.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K040912

NOV 1 6 2004

K040912

19. 510(k) Summary

510(k) SUMMARY – Safety and Effectiveness

Hydrogel Canalicular Plug

1. Submitters Name:

Partners In Biomaterials, Inc.
466 W. Arrow Highway, Unit H
San Dimas, California 91773
(909) 305-5400 (Phone)
(909) 305-9987 (Fax)
Contact: James Christensen
Date Prepared: April 6, 2004

2. Name of Device:

Trade Name: Hydrogel Canalicular Plug
Common Name: Hydrogel Canalicular Plug
Classification Name: Plug, Punctum

3. Predicate Device:

The proposed device, the Hydrogel Canalicular Plug, claims substantial equivalence in intended use and method of operation to the Medennium Smart Plug (K022043). Both plugs are a one-size-fits-all design that change shape upon insertion in to the canaliculus in order to block fluid flow through the canaliculus. Both plugs are semi-rigid rods prior to insertion into the canaliculus. The Hydrogel Canalicular Plug also claims substantial equivalence to collagen plugs marketed by Oasis Medical (K946357), and others, in both size and function. Both of these plugs are approximately 0.3mm diameter by 2.5mm long. When inserted into the canaliculus, they both absorb lacrimal fluids causing them to hydrate and swell to a larger diameter and longer length.

4. Description of Device:

The Hydrogel Canalicular Plug is a very high water content hydrogel plug which, when exposed to lacrimal fluids, expands to approximately three times its size to form a gel which blocks the canaliculus. In its dry state, the Hydrogel Canalicular Plug measures approximately 0.3 mm diameter by 2.5 mm long. It is supplied loaded in a disposable Inserter to assist the doctor in placement of the plug through the punctal opening. Refer to the photos and drawings of the dry Hydrogel Canalicular Plug and Inserter contained in Attachment A.

After the plug is inserted into the canaliculus, the dry hydrogel will absorb lacrimal fluids and swell. The fully hydrated plug has approximately a 95% water content. At this water content, the hydrogel becomes a gel having about the same consistency as mucus. The gel

easily deforms and takes the shape of the inside of the canaliculus. Refer to the photos of the hydrated Hydrogel Canalicular Plug contained in Attachment A.

In the event that the hydrogel plug needs to be removed, it can be easily flushed from the canaliculus. Place the tip of a syringe filled with saline through the punctal opening and into the canaliculus and gently express the hydrogel plug using a stream of saline.

5. Statement of Intended Use

The Hydrogel Canalicular Plug is intended for use in patients experiencing dry eye symptoms such as redness, burning, reflex tearing, itching, or foreign body sensations which can be relieved by blocking of the punctum.

The Hydrogel Canalicular Plug may be used in the treatment of dry eye syndrome and the dry eye component of various ocular surface diseases.

When indicated, the Hydrogel Canalicular Plug may be used after surgery of the eye to prevent complications due to dry eye and to enhance the retention of ocular medications on the eye. Patients experiencing dry eye related contact lens problems may also be aided by the Hydrogel Canalicular Plug.

6. Comparison to Predicate

The proposed device, the Hydrogel Canalicular Plug, claims substantial equivalence in intended use and method of operation to the Medennium Smart Plug (K022043). Both plugs are a one-size-fits-all design that change shape upon insertion in to the canaliculus in order to block fluid flow through the canaliculus. Both plugs are semi-rigid rods measuring approximately 0.35mm in diameter prior to insertion into the canaliculus. After insertion, both plugs increase in diameter to approximately 1mm diameter in order to block flow through the canaliculus.

The Hydrogel Canalicular Plug also claims substantial equivalence to collagen plugs marketed by Oasis Medical (K946357), and others, in both size and function. Both of these plugs semi-rigid rods measuring approximately 0.35mm diameter by 2.5mm long prior to insertion. They both are inserted through the punctum and reside totally within the canaliculus. After insertion into the canaliculus, they both absorb lacrimal fluids causing them to hydrate and swell to a larger diameter and to a longer length.